DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 24, 2015

Deltex Medical Limited
% Neil Armstrong
RA Advisor To Deltex Medical
MeddiQuest Limited
Quest Science
Herlington House, Orton Malborne
Peterborough, PE2 5XS United Kingdom

Re: K150347
Trade/Device Name: Deltex Medical CardioQ-EDM+ / Deltex Medical CardioQ-EDM
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: June 16, 2015
Received: June 22, 2015

Dear Neil Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

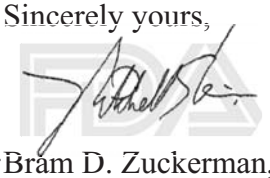
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150347

Device Name
Deltex Medical CardioQ-EDM+ / Deltex Medical CardioQ-EDM

Indications for Use *(Describe)*

The Deltex Medical CardioQ-EDM+ / Deltex Medical CardioQ-EDM cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The Deltex Medical CardioQ-EDM+ / Deltex Medical CardioQ-EDM beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Preparation Date:

July 24, 2015

Owner's Name

This traditional 510(k) is now submitted by:

Graham Lowe
Marketing & Operations Director

was originally submitted as a special 510(k) by:

Paul Dwane
Quality and Production Director

For and on behalf of the Owner:

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e-mail: graham.lowe@deltexmedical.com

Classification name:

Cardiovascular Blood Flowmeter
21CFR 870.2100
DPW

Common/Usual Name:

Esophageal Doppler Monitor

Proprietary Name:

Deltex Medical CardioQ-EDM+ / Deltex Medical CardioQ-EDM

Establishment Registration Number:

The device will be manufactured by:

Deltex Medical Ltd
Terminus Road
Chichester
West Sussex PO19 8TX
United Kingdom
Establishment Registration Number 9680933

Substantial Equivalence:

The Deltex Medical CardioQ-EDM series are substantially equivalent in design, use and materials to the: Deltex Medical CardioQ-EDM+, 510(k) number: K132139 and Deltex Medical CardioQ-EDM, 510(k) number: K111542, only the software and related labeling has been updated to introduce a second formula to the formula and body surface area algorithms, that extends the range of volumetric calculations permits the software to recognize and select the correct formula for future additions to the probe range without further update. The software will be suitable for the Deltex Medical CardioQ-EDM Series:

Deltex Medical Limited, Deltex Medical CardioQ-EDM+ - K132139

Deltex Medical Limited, Deltex Medical CardioQ-EDM - K111542

The Deltex Medical CardioQ-EDM series is made of the same materials as the Deltex Medical Limited, Deltex Medical CardioQ-EDM series - K132139 and K111542.

The Deltex Medical CardioQ-EDM series is manufactured by the same processes as the Deltex Medical Limited, Deltex Medical CardioQ-EDM series - K132139 and K111542.

The Deltex Medical CardioQ-EDM series is non-sterile.

Modified and draft labeling for the Deltex Medical CardioQ-EDM series has been submitted.

Description of Product:

The Deltex Medical CardioQ-EDM series are medical instruments designed to monitor cardiac function and fluid status. The CardioQ-EDM series combine Doppler measurement of the blood flow (4MHz continuous wave ultrasound) with Pulse Pressure Waveform Analysis (PPWA) to monitor and quantify the blood flow in the descending thoracic aorta and hence calculate other clinically significant information.

This 510(k) is submitted for clearance of a minor software change that will allow use in conjunction the KDP72 probe on additional pediatric patients K142932 of the Deltex Medical CardioQ-EDM+, K132139, and the Deltex Medical CardioQ-EDM, K111542.

Only the software and related labeling has been updated to introduce a second formula and body surface area algorithms: this extends the range of volumetric calculations and a second change will permit the software to recognize future additions to the probe range and select the correct formula without further update. In all other respects the product is the same as the predicate device.

The same software will be suitable for both the Deltex Medical CardioQ-EDM+ and the Deltex Medical CardioQ-EDM (collectively referred to as the CardioQ-EDM Series).

Intended use:

The Deltex Medical CardioQ-EDM series are medical instruments designed to monitor cardiac function and fluid status, providing clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

Indications for use:

The Deltex Medical CardioQ-EDM+ / Deltex Medical CardioQ-EDM cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The Deltex Medical CardioQ-EDM+ / Deltex Medical CardioQ-EDM beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

Additional Feature:

In addition, the Deltex Medical CardioQ-EDM+ includes a function to calculate arterial blood pressure based parameters from an output slaved from a vital signs monitor.

Testing:

The changes covered in this special 510(k) do not affect the ultrasonic performance of the device or the measurement of linear data but only the identification of the probe and subsequent calculation of volumetric data. The subject device's performance in this respect is as safe and effective as the predicate devices.

Testing is included to demonstrate the probe is correctly identified and the appropriate formula and Body Surface Area algorithm selected based on that identification.

Code examination is also included to demonstrate that the software correctly implements the formula and algorithms and simulation testing conducted to demonstrate the values displayed match those calculated "by hand".

The tests reported in the submission and the supplements demonstrate that the device is as safe, as effective, and performs as well as the predicate devices CardioQ-EDM (K111542) and CardioQ-EDM+ (K132139).

Hence Deltex Medical concludes that the subject device is substantially equivalent to the predicate devices.